

## PATENT ABSTRACTS OF JAPAN

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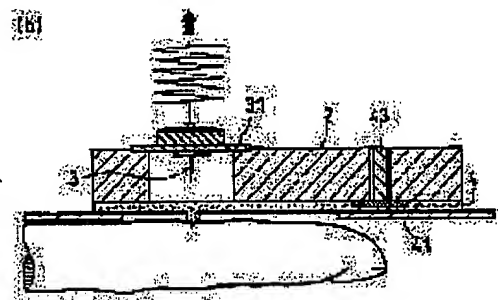
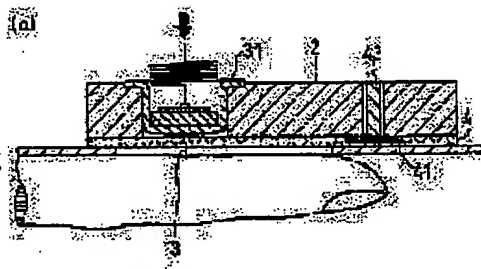
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### (54) BODY FLUID COLLECTING TOOL AND BODY FLUID ANALYZER USING THE SAME

(57)Abstract:

**PROBLEM TO BE SOLVED:** To provide a body fluid collecting tool capable of collecting body fluid not by suction and displaying data, by setting a member capable of transmitting body fluid so as to be penetrated with a penetrating needle.

**SOLUTION:** A base body 2 must comprise a material with rigidity and a penetrating needle holding member 31 a material with elasticity. The penetrating needle holding member 31 is hit by a hammer, etc., connected with a spring to be deformed downward, and a penetrating needle 3 is pushed out downward therewith. The pushed out penetrating needle 3 penetrates through a body fluid transmission member 4 and a finger mounted thereunder, then returns to the original position by the elasticity of the penetrating needle holding member 31. Though the finger penetrated bleeds, the bled blood is absorbed by the body fluid transmission member 4 and reaches an electrode 41 (42) by the capillary phenomenon, etc. Detected matters in the blood are converted to electric signals and transmitted to a sensor set in this body fluid analyzer through a lead wire 43 and measured values are displayed on a display part.



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TECHNICAL FIELD

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[Field of the Invention] This invention relates to the body fluid analysis apparatus which can analyze the body fluid extraction instrument which can extract body fluid, such as blood and a decoction between cells, and the detected matter contained in the extracted body fluid.

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PRIOR ART

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[Description of the Prior Art] The check system using the singularity of biomaterials, such as current, an enzyme, and an antibody, is extensively used for a clinical specimen, food evaluation, environmental measurement, etc. Especially, since the electronic transition by the oxidation reduction reaction of a detected material is produced before and after a reaction, many oxidoreductases, such as GOD, are used as a sensor material read with an electrical signal.

[0003] As a typical thing of such check system, the blood sugar level sensor of the pocket mold used for a diabetic etc. is mentioned. In order to have measured the blood sugar level conventionally using this blood sugar level sensor, the blemish was attached to the fingertip using the reusable puncture instrument (Lancet), the blood drop was pressed out from there, and it was carrying out by making that blood drop adhere to the measurement chip with which picked out from the wrapping material and the sensor was equipped. However, when the reusable puncture instrument and the sensor had dissociated in this way, many processes which are required in performing a series of actuation are complicated, and the problem of an operation mistake also had them. Moreover, in order to contact the blood of the need minimal dose to an electrode section with the measurement chip of this blood sugar level sensor, the slit was formed for the film on lamination and an electrode through the spacer, the approach of introducing blood in a slit by capillarity was taken, and that manufacture was difficult.

[0004] Then, the blood collecting machine (refer to JP,5-95937,A and JP,5-95938,A) with which the blood collecting machine (refer to JP,5-111476,A, JP,6-311980,A, JP,6-327655,A, and JP,7-51251,A) with which the medical-application system (refer to JP,61-286738,A) by which the reusable puncture needle, the capillary tube, and the sensor were united, a reusable puncture needle, an attraction implement, and \*\*\*\*\* were united and a reusable puncture needle, an attraction implement, \*\*\*\*\*, and a sensor were united was proposed.

[0005] However, the blood collecting approach in these instruments It is what is depended on the method with which all are decompressed by the syringe, a syringe, etc. and attract blood. unless it sticks the base of a cylinder on the skin, it cannot decompress, but when the cylinder below phi1.5 mm is used, blood plugs up a hole with the former, there is a fault of bleeding stopping, and the structure of a syringe is complicated in the latter -- etc. -- there was a fault.

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**EFFECT OF THE INVENTION**

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[Effect of the Invention] The body fluid extraction instrument of this invention is easy to manufacture, and according to the body fluid analysis apparatus of this invention, can extract body fluid easily by the approach by attraction, and can analyze body fluid that it is simple and promptly.

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**TECHNICAL PROBLEM**

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[Problem(s) to be Solved by the Invention] The technical problem of this invention is offering the convenient body fluid analysis apparatus possessing a body fluid extraction instrument with easy manufacture and this body fluid extraction instrument, the means to which the bleeding volume of body fluid is made to increase, and a display while having the device in which body fluid is extracted by the approach by attraction.

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**DETAILED DESCRIPTION**

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[Detailed Description of the Invention]

[0001]

[Field of the Invention] This invention relates to the body fluid analysis apparatus which can analyze the body fluid extraction instrument which can extract body fluid, such as blood and a decoction between cells, and the detected matter contained in the extracted body fluid.

[0002]

[Description of the Prior Art] The check system using the singularity of biomaterials, such as current, an enzyme, and an antibody, is extensively used for a clinical specimen, food evaluation, environmental measurement, etc. Especially, since the electronic transition by the oxidation reduction reaction of a detected material is produced before and after a reaction, many oxidoreductases, such as GOD, are used as a sensor material read with an electrical signal.

[0003] As a typical thing of such check system, the blood sugar level sensor of the pocket mold used for a diabetic etc. is mentioned. In order to have measured the blood sugar level conventionally using this blood sugar level sensor, the blemish was attached to the fingertip using the reusable puncture instrument (Lancet), the blood drop was pressed out from there, and it was carrying out by making that blood drop adhere to the measurement chip with which picked out from the wrapping material and the sensor was equipped. However, when the reusable puncture instrument and the sensor had dissociated in this way, many processes which are required in performing a series of actuation are complicated, and the problem of an operation mistake also had them. Moreover, in order to contact the blood of the need minimal dose to an electrode section with the measurement chip of this blood sugar level sensor, the slit was formed for the film on lamination and an electrode through the spacer, the approach of introducing blood in a slit by capillarity was taken, and that manufacture was difficult.

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[0005] However, the blood collecting approach in these instruments It is what is depended on the method with which all are decompressed by the syringe, a syringe, etc. and attract blood. unless it sticks the base of a cylinder on the skin, it cannot decompress, but when the cylinder below  $\phi 1.5$  mm is used, blood plugs up a hole with the former, there is a fault of bleeding stopping, and the structure of a syringe is complicated in the latter -- etc. -- there was a fault.

[0006]

[Problem(s) to be Solved by the Invention] The technical problem of this invention is offering the convenient body fluid analysis apparatus possessing a body fluid extraction instrument with easy



manufacture and this body fluid extraction instrument, the means to which the bleeding volume of body fluid is made to increase, and a display while having the device in which body fluid is extracted by the approach by attraction.

[0007]

[Means for Solving the Problem] Even if it was not based on the attraction approach in view of the above-mentioned technical problem by preparing the member which this invention person etc. may deliver body fluid as a result of wholeheartedly research so that a reusable puncture needle may penetrate, body fluid could be extracted easily, and a header and this invention were completed for the ability of body fluid to be analyzed that it is simple and promptly.

[0008] That is, this invention is a body fluid extraction instrument characterized by coming at least to provide the humoral transmission member which may be transmitted to the location of a request of body fluid, and the puncture member which may penetrate said humoral transmission member. Moreover, this invention is a body fluid analysis apparatus characterized by coming to provide said body fluid extraction instrument, the means to which the bleeding volume of body fluid is made to increase, and the display which displays the analysis result of the extracted body fluid at least.

[0009]

[Function] With the body fluid extraction instrument of this invention which has the humoral transmission member which consists of an ingredient which has absorptivity, and the puncture member which may penetrate the humoral transmission member, the body fluid which bled moves by capillarity etc. in the inside of a humoral transmission member, and an enzyme electrode is contacted. Moreover, with the body fluid extraction instrument of this invention which has the humoral transmission member which consists of an ingredient of non-absorptivity, and the puncture member which may penetrate the humoral transmission member, the body fluid which bled moves by capillarity etc. in the opening between the skin and a humoral transmission member, and an enzyme electrode is contacted.

[0010] Therefore, according to the body fluid extraction instrument of this invention, when the cylinder below the problem that it cannot decompress unless it sticks the base of the problem accompanying the approach of collecting blood by attraction, i.e., a cylinder, on the skin, and  $\phi 1.5$  mm is used, body fluid can plug up a hole and can solve the problem that bleeding will stop, the problem that the structure of a syringe is complicated, etc. Moreover, it is not necessary to establish the special means for contacting body fluid to an enzyme electrode etc., and a series of actuation processes which analysis takes can be reduced.

[0011] In the body fluid extraction instrument of this invention, detected matter various by one inspection can be measured by preparing the enzyme electrode of a class with which plurality differs. According to the body fluid analysis apparatus possessing the above-mentioned body fluid extraction instrument, the means to which the bleeding volume of body fluid is made to increase, and a display of this invention, a general user cannot need skill, but can extract body fluid easily and promptly, and can analyze the detected matter by one-touch.

[0012] If the above-mentioned body fluid extraction instrument is made into a cartridge-type, it can be made throwing away and bacterial infection etc. can be prevented. If this body fluid extraction instrument is packed, it is still more sanitarily safe. Moreover, if this body fluid extraction instrument is used as the cartridge of 1 by plurality, it can let out this body fluid extraction instrument one after another, and body fluid can be analyzed continuously.

[0013]

[Embodiment of the Invention] Hereafter, this invention is explained to a detail with reference to a drawing. Here, the body fluid in this invention means the liquid which may bleed from a living body by carrying out a puncture, for example, blood, the decoction between cells, etc. are mentioned.

[0014] The perspective view of a body fluid extraction instrument with an example of this invention is shown in drawing 1. Moreover, it is drawing 2 (a) about the A-A sectional view of the body fluid extraction instrument 1 in drawing 1. The decomposition perspective view of the body fluid extraction

instrument 1 is shown in drawing 3. This body fluid extraction instrument 1 is attached in the tabular base 2 which has pores 21, 22, and 23, and a base 2 through the reusable puncture needle attachment component 31, and has the reusable puncture needle 3 contained in the pore 21, and the humoral transmission member 4 prepared in the base of a base 2. The enzyme electrode is prepared in the top face of the humoral transmission member 4, and the enzyme electrode consists of a working electrode 41 and a contrast electrode 42. Lead wire 43 is connected with each electrode 41 and 42, and it holds in the pore 22 of a base 2, and 23.

[0015] With [ a body fluid extraction instrument ] such structure, there is an advantage that the magnitude can be used as a compact. Moreover, since an electrode can be made into a plane, this electrode can be formed easily. Although a base 2 may be formed from what kind of ingredient, when it forms from the ingredient which has rigidity, in order to make a reusable puncture needle 3 project, it is necessary to form the reusable puncture needle attachment component 31 with the ingredient which has elasticity. On the other hand, when a base 2 is formed with the ingredient which has elasticity, the reusable puncture needle attachment component 31 can be formed from the ingredient which has rigidity. Especially if installation to a body fluid analysis apparatus is possible for the magnitude and the configuration of a base 2, it will not be restricted, but when the operability at the time of installation, the storability of a reusable puncture needle 3, etc. are taken into consideration, the thickness of the direction of a puncture is 2-50mm, and it is desirable that they are [ which is the polygon and diameter of 3-50mm whose one side of a cross section vertical to the direction of a puncture is 3-50mm ] circular or the configuration which combined the ellipse form, or a polygon, and circular and an ellipse form.

[0016] As an ingredient which has the rigidity which forms a base 2, plastics, the ceramics, a metal, etc. are mentioned, for example and a polyurethane rubber, synthetic rubber, etc. the textile fabrics which consist of these ingredients, a nonwoven fabric, a surgical tape ingredient, etc. are mentioned as an ingredient which has elasticity, for example. Moreover, as an ingredient which has the elasticity which forms the reusable puncture needle attachment component 31, adhesive tape etc. is mentioned, for example and plastics etc. is mentioned as an ingredient which has rigidity, for example.

[0017] A reusable puncture needle 3 is formed with an ingredient harmless to the body. As such an ingredient, a stainless steel (SUS) is desirable. Since the die length of a reusable puncture needle 3 makes the horny layer of the humoral transmission member 4 and the skin penetrate, it is desirable that it is 2-30mm. In this example, since the reusable puncture needle 3 is contained in the pore 21 of a base 2 at the times other than the time of a puncture, the injury by the installation to a body fluid analysis apparatus and the operation mistake in the case of abolition etc. can be prevented.

[0018] If a reusable puncture needle 3 can be penetrated, the humoral transmission member 4 may be formed from what kind of ingredient, and can choose either the ingredient of absorptivity, or the ingredient of non-absorptivity. As an ingredient of absorptivity, the body fluid which bled from the body by the puncture is absorbable, and as long as even an enzyme electrode can transport the absorbed body fluid by capillarity etc., what kind of thing may be used. As such an ingredient, paper, textile fabrics, a nonwoven fabric, a porous body, etc. can be used, for example. As paper, a cellulose filter paper etc. is mentioned, as textile fabrics and a nonwoven fabric, what consists of a cellulose, a regenerated cellulose, cellulose acetate, silk, cotton, a polyamide, polyester, the poly acrylic, polyolefine, polyurethane, nylon, etc. is mentioned, and a glass filter, a nylon membrane, a nitrocellulose membrane, a cellulose acetate membrane, a polyvinylidene fluoride membrane, a regenerated-cellulose membrane, a foaming cellulose sheet, etc. are mentioned as a porous body. Also in these absorptivity ingredients, a cellulose filter paper, a glass filter, and a polyester nonwoven fabric are more suitable than points, such as rigidity and absorptivity ability.

[0019] Since the amount of body fluid is limited to the water absorption capacity of the absorptivity ingredient when using an absorptivity ingredient, inspecting with the specimen liquid of a constant rate is possible. Moreover, since the large surface area of an electrode can be taken, it is also possible to raise sensibility. Although it is not necessary to establish a punching process specially in order for a reusable

puncture needle 3 to penetrate such an absorptivity ingredient, depending on the case, the pore of 3 copies of reusable puncture needle excessive use may be prepared. When forming the humoral transmission member 4 from an absorptivity ingredient, the thickness of the humoral transmission member 4 specifically has [ that what is necessary is just to set up suitably in consideration of the die length of a reusable puncture needle 3, the bleeding volume of body fluid, the distance from a puncture part to an electrode, etc. ] desirable about 2-2000 micrometers.

[0020] On the other hand, as long as even an electrode can transport between the bodies the body fluid which bled from the body by the puncture by capillarity etc. as an ingredient of non-absorptivity, what kind of thing may be used. As such an ingredient, polyethylene, polyethylene terephthalate, polystyrene, triacetyl cellulose, etc. are mentioned. Although it is not necessary to establish a punching process specially by forming so that a reusable puncture needle 3 may penetrate such a non-absorptivity ingredient, when a reusable puncture needle 3 cannot be penetrated, it is necessary to prepare the pore (puncture hole) of 3 copies of reusable puncture needle excessive use.

[0021] When forming the humoral transmission member 4 from a non-absorptivity ingredient, the thickness of the humoral transmission member 4 specifically has [ that what is necessary is just to set up suitably in consideration of the die length of a reusable puncture needle 3 ] desirable about 2-2000 micrometers. A working electrode 41 contains the oxidoreductase and electron transport matter of the quality of a detected material besides the conductive matter to the contrast electrode 42 being formed from a conductive ingredient. As a conductive ingredient (matter), metal particles, such as metal pastes, such as metals, such as gold, silver, platinum, and copper, a golden paste, a silver paste, and a copper paste, carbon paste, gold colloid, and silver colloid, indium oxide, etc. are mentioned. The conductive matter in a working electrode 41 has the role which transmits the electrochemical change by the enzyme reaction to lead wire 43.

[0022] An oxidoreductase recognizes the quality of a detected material and produces electrochemical change through an oxidation reduction reaction. Although the oxidoreductase used in this invention will not be limited especially if the oxidation reduction reaction of the quality of a detected material is performed, its stable thing is desirable in respect of the preservation in the dryness from the production process of an enzyme electrode to an activity, and its thermostable enzyme like the thermophilic-bacteria origin by the case is desirable. As main oxidoreductases, glucose oxidase, glucose oxidase, pyruvate-oxidase, and D- or a L-amino acid oxidase, amine oxidase, cholesterol oxidase, choline oxidase, a urate oxidase, ascorbate oxidase, alcohol dehydrogenase, pyruvate dehydrogenase, a folic-acid dehydrogenase, etc. are mentioned.

[0023] The electron transport matter has the function to transmit transfer of the local electron produced in the reactive site of an enzyme to the conductive matter through this electron transport matter. As such electron transport matter, polypyrrole, a ferrocene, a ferrocene derivative, a nicotinamide derivative, a flavin derivative, a quinone, a quinone derivative, etc. are mentioned. These electron transport matter carries the electronic transition between an enzyme and the conductive matter, when it is mixed with an enzyme solution or is directly embellished by the enzyme.

[0024] A working electrode 41 and the contrast electrode 42 may contain the surfactant for improving the permeability of protein, such as BSA for stabilizing PVP for making the salts which have the buffer action other than the above component, and an electrode fix to a base material, PVA and a binder component like a carrageenan, and an enzyme, and casein, a saccharide, and specimen liquid, phospholipid, etc. Moreover, you may pretreat it being immersed in a surfactant, phospholipid, etc. and drying this humoral transmission member 4 after that also about the base material slack humoral transmission member 4, in order to improve the absorptivity and permeability of specimen liquid etc.

[0025] These electrodes 41 and 42 can be formed by applying or sticking an electrode material on the humoral transmission member 4. In order to form a working electrode 41 in the humoral transmission member 4 especially, a conductive ingredient, an electron transport ingredient, and an oxidoreductase are mixed, and there are an approach of applying at one process and the approach of fixing an electron

transport ingredient and an oxidoreductase, after forming an electrode substrate with a conductive ingredient. In any case, screen printing, the roll coating method, a dispenser, an ink jet, vacuum deposition, a nonelectrolytic plating method, etc. can be used at patterning. However, it is more desirable to fix an enzyme, after forming an electrode substrate under the environment which cannot be easily stabilized by enzymes, such as a case where the metal paste which requires hot sintering is used, and vacuum deposition, a nonelectrolytic plating method, also in order not to carry out deactivation of the enzyme. Screen printing, the roll coating method, a dispenser, an ink jet, etc. can perform immobilization of an enzyme.

[0026] By the approach of applying at one process, a conductive ingredient like carbon black, an oxidoreductase like GOD, and an electron transport ingredient like polypyrrole can be kneaded with an organic solvent like ethyl alcohol, for example, and a working electrode 41 can be formed with screen printing etc.

[0027] Or after fixing an enzyme to the metal sol particle in a water solution, using a metal sol particle as a conductive ingredient, a working electrode 41 can be formed with a dispenser, an ink jet, roll coating, screen printing, etc. with the electron transport matter. If an electrode is prepared by the water-solution system, it can form at one process, with the activity of an enzyme held. In the case of gold colloid, a metal sol particle can be prepared by returning chloroauric acid with a suitable reducing agent. Reaction time with a reducing agent and the concentration of a reducing agent can adjust the particle size of a metal sol particle. In order to fix an enzyme to a metal sol particle, after removing the unreacted liquid contained in supernatant liquid by centrifugal separation after preparing a metal sol particle, it is fixable by adding an enzyme under stabilizer existence, such as BSA and sugar, in the buffer solution of pH of a proper reaction condition.

[0028] the condition of having formed in the humoral transmission member which consists an electrode of an absorptivity ingredient as mentioned above -- drawing 4 (a) and (b) It is shown in an enlarged drawing: drawing 4 (a) \*\*\*\* -- an electrode 40 is covered on the front face of 4t of organizations of an absorptivity ingredient -- having -- \*\*\*\* -- drawing 4 (b) \*\*\*\* -- while being covered by the front face of 4t of organizations, the opening of 4t of organizations is filled up.

[0029] Although electrodes 41 and 42 could be formed in any of the top face of the humoral transmission member 4, or an underside when the humoral transmission member 4 was formed from the ingredient of absorptivity, when it forms from the ingredient of non-absorptivity, it is drawing 2 (b). It is necessary to prepare in the underside of the humoral transmission member 4 so that it may be shown. As for each electrode, it is desirable to form in as near from a puncture part a location as possible, in order to stop the bleeding volume of body fluid a little, and in order to make the resistance by body fluid small, as for a working electrode 41 and the contrast electrode 42, it is desirable to make it approach and to form.

[0030] the body fluid extraction instrument of this invention -- drawing 5 (a) and (b) The laminating of the sheet 4b which consists of an ingredient of this water absorption layer 4a and non-absorptivity may be carried out so that it may be shown, and humoral transmission member (water absorption layer) 4a which consists of an ingredient of absorptivity may turn down. In this case, enzyme electrodes 41 and 42 It may be formed in which [ of water absorption layer 4a or sheet 4b ] side that what is necessary is to just be prepared among both. The laminating of water absorption layer 4a and sheet 4b can be performed by the approach of applying absorptivity powder like the approach of sticking by pressure using a binder, binders, such as PVP, etc. or a carboxymethyl cellulose, and a microcrystal cellulose to sheet 4b etc.

[0031] The body fluid extraction instrument of this invention may have two or more enzyme electrodes. By using the enzyme of a different class according to the detected matter respectively, many items are simultaneously detectable. Two or more enzyme electrodes may be prepared in the same base material, and as shown in drawing 6, 'the enzyme electrodes 41 and 42 of a class which consists of -- and is different on each class, 41', 42' may be prepared 4n of two or more layers which consist a humoral transmission member of an absorptivity ingredient. [ 4n ] In the case of the former, a base material may

be formed between the sheets and water absorption layers which may consist of an absorptivity ingredient, and may consist of a non-absorptivity ingredient, or consist of a non-absorptivity ingredient. the latter -- a case -- body fluid -- each class -- sequential -- osmosis -- carrying out -- each -- a layer -- preparing -- having had -- an enzyme electrode -- reaching -- although -- an electrode -- comrades -- contact -- preventing -- a sake -- drawing 7 -- being shown -- as -- an enzyme electrode -- forming -- having had -- a layer -- four -- n -- four -- n -- ' -- four -- n -- ' -- ' -- between -- absorptivity -- having -- a spacer -- a layer -- four -- m -- four -- m -- ' -- preparing -- a thing -- being desirable .

[0032] Drawing 8 (a) and (b) It is the mimetic diagram showing an example of the body fluid (here blood) extraction with the body fluid extraction instrument 1 using the humoral transmission member 4 formed from the ingredient of absorptivity. In this example, a base 2 shall consist of an ingredient which has rigidity, and the reusable puncture needle attachment component 31 shall consist of an ingredient which has elasticity. The reusable puncture needle attachment component 31 is struck by the hammer connected with the spring, and deforms caudad, and a reusable puncture needle 3 is caudad extruded with it. The extruded reusable puncture needle 3 penetrates the humoral transmission member 4, and after it carries out the puncture of the finger with which the bottom of it was equipped, it returns to the original location by the elasticity of the reusable puncture needle attachment component 31. Although the finger by which the puncture was carried out bleeds, the blood is absorbed by the humoral transmission member 4, and reaches electrodes 41 and 42 by capillarity etc. The detected matter in blood is changed into an electrical signal, and is sent to the sensor formed in the body fluid analysis apparatus through lead wire 43.

[0033] Drawing 9 (a) and (b) It is the mimetic diagram showing an example of the blood extraction with the body fluid extraction instrument 1 using the humoral transmission member 4 formed from the ingredient of non-absorptivity. In this example, a base 2 shall consist of an ingredient which has elasticity, and the reusable puncture needle attachment component 31 shall consist of an ingredient which has rigidity. The reusable puncture needle attachment component 31 is struck by the hammer connected with the spring, and is made to transform a base 2. A reusable puncture needle 3 is caudad extruded by deformation of a base 2, and penetrates the humoral transmission member 4 according to it. And after carrying out the puncture of the finger with which the bottom of the humoral transmission member 4 was equipped, it returns to the original location by the elasticity of a base 2. Although the finger by which the puncture was carried out bleeds, by capillarity etc., the blood moves between the humoral transmission member 4 and fingers, and reaches electrodes 41 and 42. The detected matter in blood is changed into an electrical signal, and is sent to the sensor formed in the body fluid analysis apparatus through lead wire 43.

[0034] In addition, although the electrode was prepared in the humoral transmission member in this example, this invention is not limited to this but may form the means which takes out an electrical signal from a humoral transmission member in a body fluid analysis apparatus side. For example, the conductive member of the shape of a cylinder corresponding to the pores 22 and 23 of a base 2 is installed in a body fluid analysis apparatus, and if it is made to drive so that a humoral transmission member may be contacted when it equips with a body fluid extraction instrument, the detected matter can be measured even if it does not prepare an electrode and lead wire like this example. Moreover, although this example explained the detected matter taking the case of the approach of measuring electrochemically, a means to detect optically using a GOD-chromophoric substrate etc. is also applicable.

[0035] This body fluid extraction instrument 1 can be made into a cartridge-type, and can be used for a body fluid analysis apparatus. By it, throwing away becomes possible and bacterial infection etc. can be prevented. Moreover, if this body fluid extraction instrument 1 is packed, it becomes safe still more sanitarily and deactivation of an enzyme can also be prevented. The sectional view of the body fluid extraction instrument 1 which twisted package object 11 and was packed is shown in drawing 10. Although this package object 11 may be formed from what kind of thing as long as it has airtightness,

the laminate film which carried out two or more laminatings of polyethylene, nylon, the polypropylene, etc., for example to aluminum foil can be used for it. It is desirable to perform a package by the aseptic condition.

[0036] If the body fluid extraction instrument 1 is used as the cartridge of 1 by plurality when making the body fluid extraction instrument 1 into a cartridge-type, it can let out a body fluid extraction instrument one after another, and body fluid can be analyzed continuously. Drawing 11 is the sectional view showing the condition of having loaded the cartridge electrode holder 12 of 1 with five body fluid extraction instruments 1 respectively packed with the package object 11.

[0037] Next, the perspective view of the body fluid extraction instrument by another example of this invention is shown in drawing 12. moreover, the mimetic diagram showing an example of the body fluid extraction which used body fluid extraction instrument 1' for drawing 13 for the top view of the humoral transmission member 4 of body fluid extraction instrument 1' in drawing 12 -- drawing 14 (a), (b), and (c) It is shown. Body fluid extraction instrument 1' has the cylinder-like cylinder 24, the reusable puncture needle attachment component 31 which can slide on the inside of a cylinder 24, the reusable puncture needle 3 attached in the reusable puncture needle attachment component 31, and the humoral transmission member 4 prepared in the soffit of a cylinder 24. As shown in drawing 13, the working electrode 41 and the contrast electrode 42 are formed in the humoral transmission member 4, and wiring 44 is formed in each electrode. Although each electrodes 41 and 42 and wiring 44 may be formed in any of the top face of the humoral transmission member 4, or an underside, when the humoral transmission member 4 consists of an ingredient of non-absorptivity, it is necessary to prepare them in an underside.

[0038] Especially if installation to a body fluid analysis apparatus is possible for the magnitude and the configuration of a cylinder 24, it will not be restricted, but when the operability at the time of installation, the storability of a reusable puncture needle 3, etc. are taken into consideration, the height of the direction of a puncture is 2-50mm, and it is desirable that they are [ whose cross section vertical to the direction of a puncture is the diameter of 3-50mm ] circular or the configuration which combined the ellipse form, the polygon whose one side is 3-50mm or the polygon, and circular and an ellipse form.

[0039] Also in this body fluid extraction instrument 1', the laminating of the humoral transmission member (water absorption layer) which consists of an ingredient of absorptivity, and the sheet which consists of an ingredient of non-absorptivity may be carried out, and two or more enzyme electrodes may be prepared. Two or more enzyme electrodes may be prepared in the same base material, as shown in drawing 15, a humoral transmission member may be constituted from two or more layers which consist of an absorptivity ingredient, and the enzyme electrode of a class which is different on each class may be prepared. Even case [ like drawing 15 ], an electrode may be prepared between the sheets which consist of a humoral transmission member which a base material may consist of an absorptivity ingredient, and may consist of a non-absorptivity ingredient, or consists of an absorptivity ingredient, and a non-absorptivity ingredient.

[0040] In body liquid extraction instrument 1', the reusable puncture needle attachment component 31 is pushed with the hammer connected with the spring, and slides caudad. By it, a reusable puncture needle 3 penetrates the humoral transmission member 4, and carries out the puncture of the finger with which the bottom of it was equipped. A reusable puncture needle 3 and the reusable puncture needle attachment component 31 return to the original location with a conventional method using an operation of a spring etc. Although the finger by which the puncture was carried out bleeds, the blood is absorbed by the humoral transmission member 4, or is transmitted in between the humoral transmission member 4 and fingers, and reaches electrodes 41 and 42. The detected matter in blood is changed into an electrical signal, and is sent to the sensor formed in the body fluid analysis apparatus through wiring 44.

[0041] Although the body fluid extraction instrument was explained above, the body fluid analysis apparatus of this invention which used this body fluid extraction instrument next is explained. In addition, in this example, a body fluid extraction instrument is considered as a measurement chip.

[0042] Drawing 16 is the perspective view of a body fluid analysis apparatus with an example of this



invention. The display 61 and the binding switch 62 with which this body fluid analysis apparatus 5 was formed in the flank of 1 of housing 6 and its housing 6, the reusable puncture needle discharge switch 63, the measurement chip installation implement 64, a test section 80, and the binding section 7, While having the cartridge electrode-holder stowage 8 and the reusable puncture needle actuator 9 which were established in the interior of housing 6 Measurement chip 81a was installed in the test section 80, and the cartridge electrode holder 82 including the measurement chips 81b, 81c, 81d, and 81e packed with the package object 83 in the cartridge electrode-holder stowage 8 is contained.

[0043] Drawing 17 (a) and (b) The measurement chip 81 contained by the cartridge electrode holder 82 is sent out at a time to a test section 80 by one measurement chip installation implement 64 so that it may be shown. Since the package object 83 is torn off from the measurement chip 81 by claw part 80a prepared in the test section 80 at this time, the measurement chip 81 is installed in a test section 80 in the safe condition for reasons of sanitation. The measurement chip installation implement 64 is formed possible [ sliding ] to the cartridge electrode holder 82, and after it sends out the measurement chip 81, it is returned to the original location with a spring 84. The measurement chips 81b, 81c, 81d, and 81e left behind after measurement chip 81a was sent out are pressed with a spring 85, and measurement chip 81b moves them to the location which may be sent out by the measurement chip installation implement 64.

[0044] Although point 64a of an installation implement is horizontally suitable in the usual condition, for example although you may have what kind of configuration as long as it can send out the measurement chip 81 to a test section 80, and the measurement chip 81 may pass through the bottom of the measurement chip installation implement 64, the measurement chip installation implement 64 In case it is used, if the measurement chip installation implement 64 is touched, when installation implement point 64a contacts the back end section of the measurement chip 81 toward a slanting lower part and slides the measurement chip installation implement 64, the configuration which can send out the measurement chip 81 to a test section 80 can be taken.

[0045] In addition, although the graphic display was not carried out, it is desirable to prepare extrusion and the abolition function which can discard the measurement chip after measurement, without a test subject touching directly. As long as the package object 83 is desorbed from the measurement chip 81 with a desired means, it may have what kind of configuration, but when making it torn off for example, by claw part 80a prepared in the test section 80, can prepare handle part 83a into which the head was divided, and can take a configuration with which claw part 80a enters between the broken part.

[0046] It is prepared in order for the binding section 7 to make the bleeding volume of body fluid increase, and a finger is inserted into this. In this example, although the binding section 7 has become cylinder-like, it can choose various configurations, such as the shape of a ring, and telescopic. Since there is individual difference in the size of the finger of an operating personnel-ed, it is desirable that they are the ingredient which has elasticity, and the thing which can adjust a bore with a belt etc.

[0047] The binding member 71 which makes a finger pressed and congested is formed in the interior of the binding section 7. Except the time of measurement, although this binding member 71 contacts a finger lightly and is fixing that finger to it, at the time of the need (at the time [ For example, a puncture direct front stirrup ] before a puncture - of a puncture), a bore becomes small, and it makes the blood vessel of a finger congested while it presses a finger, and can obtain the body fluid of an amount enough at the time of a puncture. Moreover, the body fluid of an amount can be enough pressed out from a puncture part by pressing a finger immediately after a puncture. Although you may consist of what kind of thing as a binding member 71 as long as it can make a finger pressed and congested, the thing using impregnation of air, the thing using the draw-down of the belt by actuation of a motor etc., etc. can be used like the application-of-pressure band used for measurement of blood pressure, for example.

[0048] The reusable puncture needle (refer to drawing 1 - drawing 3 , and drawing 8 ) of the measurement chip 81 installed in the test section 80 is hammered out with the hammer 92 connected with the spring 91 in the reusable puncture needle actuator 9, and projects from a humoral transmission member. What is necessary is just to establish a means which operates that what is necessary is just to

perform actuation of a hammer 92 with a conventional method when the reusable puncture needle discharge switch 63 is pushed. In order to raise visibility, forming as greatly as possible is desirable, and when a display 61 inserts a finger in the binding section 7, it is desirable to prepare in the location in which it does not hide with the finger.

[0049] An example of the approach of measuring the detected matter in blood is explained using the above-mentioned body fluid analysis apparatus 5. First, the cartridge electrode holder 82 is inserted in the cartridge electrode-holder stowage 8, and the measurement chip 81 is sent out to a test section 80 with the measurement chip installation implement 64. Next, a finger is inserted in the binding section 7 (refer to drawing 18), and the binding switch 62 is turned on. Then, a finger is pressed by the binding member 71 and congested. If the reusable puncture needle discharge switch 63 is turned on in this condition, the reusable puncture needle of the measurement chip 81 will be hammered out with the hammer 92 connected with the spring 91, and will carry out the puncture of a projection and the finger from a humoral transmission member. The blood which bled from the finger is absorbed by the humoral transmission member, or is transmitted in between a humoral transmission member and fingers, reaches an electrode, and the detected matter in blood serves as an electrical signal, it is sent to a sensor, and measured value is shown in a display 61.

[0050] Moreover, another example of the approach of measuring the detected matter in blood is explained using the above-mentioned body fluid analysis apparatus 5. Although it is the same as that of the above until it inserts the cartridge electrode holder 82 in the cartridge electrode-holder stowage 8, and sends out the measurement chip 81 to a test section 80 and inserts a finger in the binding section 7 after that with the measurement chip installation implement 64 next, the reusable puncture needle discharge switch 63 is turned on. Then, the reusable puncture needle of the measurement chip 81 is hammered out with the hammer 92 connected with the spring 91, and carries out the puncture of a projection and the finger from a humoral transmission member. After carrying out a puncture, the binding switch 62 is turned on. Blood is pressed out from the part which the binding member 71 pressed the finger and carried out the puncture by it. The blood which bled is absorbed by the humoral transmission member, or is transmitted in between a humoral transmission member and fingers, reaches an electrode, and the detected matter in blood serves as an electrical signal, it is sent to a sensor, and measured value is shown in a display 61.

[0051] In addition, although the perspective view of body fluid analysis apparatus 5' by another example of this invention which used body fluid extraction instrument 1' mentioned above is shown in drawing 19 and drawing 20, if the fundamental configuration is the same as that of the above-mentioned body fluid analysis apparatus 5 and the reusable puncture needle discharge switch 63 is turned on, the hammer 92 connected with the spring 91 begins to beat the reusable puncture needle attachment component 31, and by it, a reusable puncture needle 3 will be extruded, it will penetrate the humoral transmission member 4, and will carry out the puncture of the finger. What is necessary is to read the echo of light which carried out incidence to the test section, and just to use the device to evaluate, in detecting optically using a GOD-chromophoric substrate etc. although the above example explained the detected matter taking the case of the approach of measuring electrochemically.

[0052] According to the body fluid analysis apparatus of such this invention, by simple switch actuation, after equipping with a measurement chip or a cartridge, while being able to perform a series of actuation processes of pressure of pressure of a finger, a puncture, detection and the display of measured value or a puncture, and a finger, detection, and a display of measured value continuously, inspection can be substituted for one-touch. Moreover, since this equipment possesses all of the means which takes out a puncture member, a humoral transmission member, an electrode, or an electrical signal, the means to which the bleeding volume of body fluid is made to increase, and a display, a general user does not need skill but can use it easily and promptly.

[0053] As mentioned above, although this invention was explained to the detail using the drawing, this invention can perform various modification, unless it deviates from the thought of this invention,



without being limited to this. For example, the thing of the shape of two rollers or a wash clip is used instead of a binding member, and body fluid can be pressed out from the skin.

[0054]

[Example] Hereafter, although an example explains this invention still more concretely, the range of this invention is not limited to these examples.

(Example 1) The phosphate buffer (pH7.3) containing a golden sol particle (particle size of about 40nm) and glucose oxidase was agitated, and the enzyme was fixed. Polypyrrole is mixed in this solution and it is a working-electrode component solution (a). It carried out. On the other hand, it is a working-electrode component solution (a). Working-electrode component solution which fixed cholesterol oxidase to the golden sol particle instead of glucose oxidase on the same conditions (b) It prepared.

[0055] It is a working-electrode component solution (a) with a dispenser, respectively to 4n of glass fiber filter papers which formed the golden paste by screen-stencil as the contrast electrode 42 and 42' as shown in drawing 21, and 4n 'two sheets. And (b) Apply, and it is made to dry for 2 minutes at 50 degrees C, and is an enzyme electrode (A). And (B) 41 and 41' was formed. Thus, enzyme electrode (A) And (B) Spacer 4m which consists of the same glass fiber filter paper 4n of glass fiber filter papers in which 41 and 41' was formed, and 4n 'two sheets It minded, and the laminating was carried out and it considered as the humoral transmission member 4. This humoral transmission member 4 was used and body fluid extraction instrument 1" as shown in drawing 22 was manufactured.

[0056] Each electrodes 41 and 42, 41', and 42' It connected with the reader (not shown) through lead wire 43. The finger was equipped with above-mentioned body fluid extraction instrument 1", and it was made to bleed with a reusable puncture needle. Blood was transmitted to enzyme electrode (A) and (B) 41, and 41' through 4n of glass fibers, 4n', and 4m from the puncture section, and was able to detect the glucose concentration and cholesterol concentration in blood with the above-mentioned reader.

[0057] (Example 2) Ferrocene qualification GOD solution 900 which introduced the ferrocene carboxylic acid into the lysine residue of GOD through the carbodiimide mul PVP0.123 g and ethanol 100 mul It mixed and considered as the enzyme electrode component solution. As shown in drawing 23, screen-stencil was used for polystyrene sheet 4b which prepared 4h of puncture holes with a diameter of 2mm with a silver paste, and the substrate and the contrast electrode 42 of a working electrode 41 were formed in it. Furthermore, applied the above-mentioned enzyme electrode component on the working-electrode substrate using screen-stencil, and it was made to dry for 5 minutes at 50 degrees C, and considered as the enzyme electrode.

[0058] After applying completely the solution for water absorption layers which consists of microcrystal cellulose:ethanol:triton X-100=1:1:0.01 by screen-stencil and drying it for 5 minutes at 50 degrees C on polystyrene sheet 4b of the side in which the enzyme electrode was formed, it was made to dry thoroughly by the air dried. thus -- water absorption -- a layer -- four -- a -- having formed -- a sheet -- using it -- water absorption -- a layer -- four -- a -- an underside -- becoming -- making -- drawing 24 -- being shown -- as -- body fluid -- extraction -- an instrument -- one -- " -- having manufactured . They are each electrodes 41 and 42 like an example 1. It measured by connecting with a reader. Consequently, the glucose concentration in blood was detectable.

[0059]

[Effect of the Invention] The body fluid extraction instrument of this invention is easy to manufacture, and according to the body fluid analysis apparatus of this invention, can extract body fluid easily by the approach by attraction, and can analyze body fluid that it is simple and promptly.

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[Translation done.]

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MEANS

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[Means for Solving the Problem] Even if it was not based on the attraction approach in view of the above-mentioned technical problem by preparing the member which this invention person etc. may deliver body fluid as a result of wholeheartedly research so that a reusable puncture needle may penetrate, body fluid could be extracted easily, and a header and this invention were completed for the ability of body fluid to be analyzed that it is simple and promptly.

[0008] That is, this invention is a body fluid extraction instrument characterized by coming at least to provide the humoral transmission member which may be transmitted to the location of a request of body fluid, and the puncture member which may penetrate said humoral transmission member. Moreover, this invention is a body fluid analysis apparatus characterized by coming to provide said body fluid extraction instrument, the means to which the bleeding volume of body fluid is made to increase, and the display which displays the analysis result of the extracted body fluid at least.

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[Translation done.]

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**OPERATION**

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[Function] With the body fluid extraction instrument of this invention which has the humoral transmission member which consists of an ingredient which has absorptivity, and the puncture member which may penetrate the humoral transmission member, the body fluid which bled moves by capillarity etc. in the inside of a humoral transmission member, and an enzyme electrode is contacted. Moreover, with the body fluid extraction instrument of this invention which has the humoral transmission member which consists of an ingredient of non-absorptivity, and the puncture member which may penetrate the humoral transmission member, the body fluid which bled moves by capillarity etc. in the opening between the skin and a humoral transmission member, and an enzyme electrode is contacted.

[0010] Therefore, according to the body fluid extraction instrument of this invention, when the cylinder below the problem that it cannot decompress unless it sticks the base of the problem accompanying the approach of collecting blood by attraction, i.e., a cylinder, on the skin, and  $\phi 1.5$  mm is used, body fluid can plug up a hole and can solve the problem that bleeding will stop, the problem that the structure of a syringe is complicated, etc. Moreover, it is not necessary to establish the special means for contacting body fluid to an enzyme electrode etc., and a series of actuation processes which analysis takes can be reduced.

[0011] In the body fluid extraction instrument of this invention, detected matter various by one inspection can be measured by preparing the enzyme electrode of a class with which plurality differs. According to the body fluid analysis apparatus possessing the above-mentioned body fluid extraction instrument, the means to which the bleeding volume of body fluid is made to increase, and a display of this invention, a general user cannot need skill, but can extract body fluid easily and promptly, and can analyze the detected matter by one-touch.

[0012] If the above-mentioned body fluid extraction instrument is made into a cartridge-type, it can be made throwing away and bacterial infection etc. can be prevented. If this body fluid extraction instrument is packed, it is still more sanitarily safe. Moreover, if this body fluid extraction instrument is used as the cartridge of 1 by plurality, it can let out this body fluid extraction instrument one after another, and body fluid can be analyzed continuously.

[0013]

[Embodiment of the Invention] Hereafter, this invention is explained to a detail with reference to a drawing. Here, the body fluid in this invention means the liquid which may bleed from a living body by carrying out a puncture, for example, blood, the decoction between cells, etc. are mentioned.

[0014] The perspective view of a body fluid extraction instrument with an example of this invention is shown in drawing 1. Moreover, it is drawing 2 (a) about the A-A sectional view of the body fluid extraction instrument 1 in drawing 1. The decomposition perspective view of the body fluid extraction instrument 1 is shown in drawing 3. This body fluid extraction instrument 1 is attached in the tabular base 2 which has pores 21, 22, and 23, and a base 2 through the reusable puncture needle attachment component 31, and has the reusable puncture needle 3 contained in the pore 21, and the humoral

transmission member 4 prepared in the base of a base 2. The enzyme electrode is prepared in the top face of the humoral transmission member 4, and the enzyme electrode consists of a working electrode 41 and a contrast electrode 42. Lead wire 43 is connected with each electrode 41 and 42, and it holds in the pore 22 of a base 2, and 23.

[0015] With [ a body fluid extraction instrument ] such structure, there is an advantage that the magnitude can be used as a compact. Moreover, since an electrode can be made into a plane, this electrode can be formed easily. Although a base 2 may be formed from what kind of ingredient, when it forms from the ingredient which has rigidity, in order to make a reusable puncture needle 3 project, it is necessary to form the reusable puncture needle attachment component 31 with the ingredient which has elasticity. On the other hand, when a base 2 is formed with the ingredient which has elasticity, the reusable puncture needle attachment component 31 can be formed from the ingredient which has rigidity. Especially if installation to a body fluid analysis apparatus is possible for the magnitude and the configuration of a base 2, it will not be restricted, but when the operability at the time of installation, the storability of a reusable puncture needle 3, etc. are taken into consideration, the thickness of the direction of a puncture is 2-50mm, and it is desirable that they are [ which is the polygon and diameter of 3-50mm whose one side of a cross section vertical to the direction of a puncture is 3-50mm ] circular or the configuration which combined the ellipse form, or a polygon, and circular and an ellipse form.

[0016] As an ingredient which has the rigidity which forms a base 2, plastics, the ceramics, a metal, etc. are mentioned, for example and a polyurethane rubber, synthetic rubber, etc. the textile fabrics which consist of these ingredients, a nonwoven fabric, a surgical tape ingredient, etc. are mentioned as an ingredient which has elasticity, for example. Moreover, as an ingredient which has the elasticity which forms the reusable puncture needle attachment component 31, adhesive tape etc. is mentioned, for example and plastics etc. is mentioned as an ingredient which has rigidity, for example.

[0017] A reusable puncture needle 3 is formed with an ingredient harmless to the body. As such an ingredient, a stainless steel (SUS) is desirable. Since the die length of a reusable puncture needle 3 makes the horny layer of the humoral transmission member 4 and the skin penetrate, it is desirable that it is 2-30mm. In this example, since the reusable puncture needle 3 is contained in the pore 21 of a base 2 at the times other than the time of a puncture, the injury by the installation to a body fluid analysis apparatus and the operation mistake in the case of abolition etc. can be prevented.

[0018] If a reusable puncture needle 3 can be penetrated, the humoral transmission member 4 may be formed from what kind of ingredient, and can choose either the ingredient of absorptivity, or the ingredient of non-absorptivity. As an ingredient of absorptivity, the body fluid which bled from the body by the puncture is absorbable, and as long as even an enzyme electrode can transport the absorbed body fluid by capillarity etc., what kind of thing may be used. As such an ingredient, paper, textile fabrics, a nonwoven fabric, a porous body, etc. can be used, for example. As paper, a cellulose filter paper etc. is mentioned, as textile fabrics and a nonwoven fabric, what consists of a cellulose, a regenerated cellulose, cellulose acetate, silk, cotton, a polyamide, polyester, the poly acrylic, polyolefine, polyurethane, nylon, etc. is mentioned, and a glass filter, a nylon membrane, a nitrocellulose membrane, a cellulose acetate membrane, a polyvinylidene fluoride membrane, a regenerated-cellulose membrane, a foaming cellulose sheet, etc. are mentioned as a porous body. Also in these absorptivity ingredients, a cellulose filter paper, a glass filter, and a polyester nonwoven fabric are more suitable than points, such as rigidity and absorptivity ability.

[0019] Since the amount of body fluid is limited to the water absorption capacity of the absorptivity ingredient when using an absorptivity ingredient, inspecting with the specimen liquid of a constant rate is possible. Moreover, since the large surface area of an electrode can be taken, it is also possible to raise sensibility. Although it is not necessary to establish a punching process specially in order for a reusable puncture needle 3 to penetrate such an absorptivity ingredient, depending on the case, the pore of 3 copies of reusable puncture needle excessive use may be prepared. When forming the humoral transmission member 4 from an absorptivity ingredient, the thickness of the humoral transmission

member 4 specifically has [ that what is necessary is just to set up suitably in consideration of the die length of a reusable puncture needle 3, the bleeding volume of body fluid, the distance from a puncture part to an electrode, etc. ] desirable about 2-2000 micrometers.

[0020] On the other hand, as long as even an electrode can transport between the bodies the body fluid which bled from the body by the puncture by capillarity etc. as an ingredient of non-absorptivity, what kind of thing may be used. As such an ingredient, polyethylene, polyethylene terephthalate, polystyrene, triacetyl cellulose, etc. are mentioned. Although it is not necessary to establish a punching process specially by forming so that a reusable puncture needle 3 may penetrate such a non-absorptivity ingredient, when a reusable puncture needle 3 cannot be penetrated, it is necessary to prepare the pore (puncture hole) of 3 copies of reusable puncture needle excessive use.

[0021] When forming the humoral transmission member 4 from a non-absorptivity ingredient, the thickness of the humoral transmission member 4 specifically has [ that what is necessary is just to set up suitably in consideration of the die length of a reusable puncture needle 3 ] desirable about 2-2000 micrometers. A working electrode 41 contains the oxidoreductase and electron transport matter of the quality of a detected material besides the conductive matter to the contrast electrode 42 being formed from a conductive ingredient. As a conductive ingredient (matter), metal particles, such as metal pastes, such as metals, such as gold, silver, platinum, and copper, a golden paste, a silver paste, and a copper paste, carbon paste, gold colloid, and silver colloid, indium oxide, etc. are mentioned. The conductive matter in a working electrode 41 has the role which transmits the electrochemical change by the enzyme reaction to lead wire 43.

[0022] An oxidoreductase recognizes the quality of a detected material and produces electrochemical change through an oxidation reduction reaction. Although the oxidoreductase used in this invention will not be limited especially if the oxidation reduction reaction of the quality of a detected material is performed, its stable thing is desirable in respect of the preservation in the dryness from the production process of an enzyme electrode to an activity, and its thermostable enzyme like the thermophilic-bacteria origin by the case is desirable. As main oxidoreductases, glucose oxidase, glucose oxidase, pyruvate-oxidase, and D- or a L-amino acid oxidase, amine oxidase, cholesterol oxidase, choline oxidase, a urate oxidase, ascorbate oxidase, alcohol dehydrogenase, pyruvate dehydrogenase, a folic-acid dehydrogenase, etc. are mentioned.

[0023] The electron transport matter has the function to transmit transfer of the local electron produced in the reactive site of an enzyme to the conductive matter through this electron transport matter. As such electron transport matter, polypyrrole, a ferrocene, a ferrocene derivative, a nicotinamide derivative, a flavin derivative, a quinone, a quinone derivative, etc. are mentioned. These electron transport matter carries the electronic transition between an enzyme and the conductive matter, when it is mixed with an enzyme solution or is directly embellished by the enzyme.

[0024] A working electrode 41 and the contrast electrode 42 may contain the surfactant for improving the permeability of protein, such as BSA for stabilizing PVP for making the salts which have the buffer action other than the above component, and an electrode fix to a base material, PVA and a binder component like a carrageenan, and an enzyme, and casein, a saccharide, and specimen liquid, phospholipid, etc. Moreover, you may pretreat it being immersed in a surfactant, phospholipid, etc. and drying this humoral transmission member 4 after that also about the base material slack humoral transmission member 4, in order to improve the absorptivity and permeability of specimen liquid etc.

[0025] These electrodes 41 and 42 can be formed by applying or sticking an electrode material on the humoral transmission member 4. In order to form a working electrode 41 in the humoral transmission member 4 especially, a conductive ingredient, an electron transport ingredient, and an oxidoreductase are mixed, and there are an approach of applying at one process and the approach of fixing an electron transport ingredient and an oxidoreductase, after forming an electrode substrate with a conductive ingredient. In any case, screen printing, the roll coating method, a dispenser, an ink jet, vacuum deposition, a nonelectrolytic plating method, etc. can be used at patterning. However, it is more desirable

to fix an enzyme, after forming an electrode substrate under the environment which cannot be easily stabilized by enzymes, such as a case where the metal paste which requires hot sintering is used, and vacuum deposition, a nonelectrolytic plating method, also in order not to carry out deactivation of the enzyme. Screen printing, the roll coating method, a dispenser, an ink jet, etc. can perform immobilization of an enzyme.

[0026] By the approach of applying at one process, a conductive ingredient like carbon black, an oxidoreductase like GOD, and an electron transport ingredient like polypyrrole can be kneaded with an organic solvent like ethyl alcohol, for example, and a working electrode 41 can be formed with screen printing etc.

[0027] Or after fixing an enzyme to the metal sol particle in a water solution, using a metal sol particle as a conductive ingredient, a working electrode 41 can be formed with a dispenser, an ink jet, roll coating, screen printing, etc. with the electron transport matter. If an electrode is prepared by the water-solution system, it can form at one process, with the activity of an enzyme held. In the case of gold colloid, a metal sol particle can be prepared by returning chloroauric acid with a suitable reducing agent. Reaction time with a reducing agent and the concentration of a reducing agent can adjust the particle size of a metal sol particle. In order to fix an enzyme to a metal sol particle, after removing the unreacted liquid contained in supernatant liquid by centrifugal separation after preparing a metal sol particle, it is fixable by adding an enzyme under stabilizer existence, such as BSA and sugar, in the buffer solution of pH of a proper reaction condition.

[0028] the condition of having formed in the humoral transmission member which consists an electrode of an absorptivity ingredient as mentioned above -- drawing 4 (a) and (b) It is shown in an enlarged drawing. drawing 4 (a) \*\*\*\* -- an electrode 40 is covered on the front face of 4t of organizations of an absorptivity ingredient -- having -- \*\*\*\* -- drawing 4 (b) \*\*\*\* -- while being covered by the front face of 4t of organizations, the opening of 4t of organizations is filled up.

[0029] Although electrodes 41 and 42 could be formed in any of the top face of the humoral transmission member 4, or an underside when the humoral transmission member 4 was formed from the ingredient of absorptivity, when it forms from the ingredient of non-absorptivity, it is drawing 2 (b). It is necessary to prepare in the underside of the humoral transmission member 4 so that it may be shown. As for each electrode, it is desirable to form in as near from a puncture part a location as possible, in order to stop the bleeding volume of body fluid a little, and in order to make the resistance by body fluid small, as for a working electrode 41 and the contrast electrode 42, it is desirable to make it approach and to form.

[0030] the body fluid extraction instrument of this invention -- drawing 5 (a) and (b) The laminating of the sheet 4b which consists of an ingredient of this water absorption layer 4a and non-absorptivity may be carried out so that it may be shown, and humoral transmission member (water absorption layer) 4a which consists of an ingredient of absorptivity may turn down. In this case, enzyme electrodes 41 and 42 It may be formed in which [ of water absorption layer 4a or sheet 4b ] side that what is necessary is to just be prepared among both. The laminating of water absorption layer 4a and sheet 4b can be performed by the approach of applying absorptivity powder like the approach of sticking by pressure using a binder, binders, such as PVP, etc. or a carboxymethyl cellulose, and a microcrystal cellulose to sheet 4b etc.

[0031] The body fluid extraction instrument of this invention may have two or more enzyme electrodes. By using the enzyme of a different class according to the detected matter respectively, many items are simultaneously detectable. Two or more enzyme electrodes may be prepared in the same base material, and as shown in drawing 6, 'the enzyme electrodes 41 and 42 of a class which consists of -- and is different on each class, 41', 42' may be prepared 4n of two or more layers which consist a humoral transmission member of an absorptivity ingredient. [ 4n ] In the case of the former, a base material may be formed between the sheets and water absorption layers which may consist of an absorptivity ingredient, and may consist of a non-absorptivity ingredient, or consist of a non-absorptivity ingredient. the latter -- a case -- body fluid -- each class -- sequential -- osmosis -- carrying out -- each -- a layer --

preparing -- having had -- an enzyme electrode -- reaching -- although -- an electrode -- comrades -- contact -- preventing -- a sake -- drawing 7 -- being shown -- as -- an enzyme electrode -- forming -- having had -- a layer -- four -- n -- four -- n -- ' -- four -- n -- ' -- ' -- between -- absorptivity -- having -- a spacer -- a layer -- four -- m -- four -- m -- ' -- preparing -- a thing -- being desirable .

[0032] Drawing 8 (a) and (b) It is the mimetic diagram showing an example of the body fluid (here blood) extraction with the body fluid extraction instrument 1 using the humoral transmission member 4 formed from the ingredient of absorptivity. In this example, a base 2 shall consist of an ingredient which has rigidity, and the reusable puncture needle attachment component 31 shall consist of an ingredient which has elasticity. The reusable puncture needle attachment component 31 is struck by the hammer connected with the spring, and deforms caudad, and a reusable puncture needle 3 is caudad extruded with it. The extruded reusable puncture needle 3 penetrates the humoral transmission member 4, and after it carries out the puncture of the finger with which the bottom of it was equipped, it returns to the original location by the elasticity of the reusable puncture needle attachment component 31. Although the finger by which the puncture was carried out bleeds, the blood is absorbed by the humoral transmission member 4, and reaches electrodes 41 and 42 by capillarity etc. The detected matter in blood is changed into an electrical signal, and is sent to the sensor formed in the body fluid analysis apparatus through lead wire 43.

[0033] Drawing 9 (a) and (b) It is the mimetic diagram showing an example of the blood extraction with the body fluid extraction instrument 1 using the humoral transmission member 4 formed from the ingredient of non-absorptivity. In this example, a base 2 shall consist of an ingredient which has elasticity, and the reusable puncture needle attachment component 31 shall consist of an ingredient which has rigidity. The reusable puncture needle attachment component 31 is struck by the hammer connected with the spring, and is made to transform a base 2. A reusable puncture needle 3 is caudad extruded by deformation of a base 2, and penetrates the humoral transmission member 4 according to it. And after carrying out the puncture of the finger with which the bottom of the humoral transmission member 4 was equipped, it returns to the original location by the elasticity of a base 2. Although the finger by which the puncture was carried out bleeds, by capillarity etc., the blood moves between the humoral transmission member 4 and fingers, and reaches electrodes 41 and 42. The detected matter in blood is changed into an electrical signal, and is sent to the sensor formed in the body fluid analysis apparatus through lead wire 43.

[0034] In addition, although the electrode was prepared in the humoral transmission member in this example, this invention is not limited to this but may form the means which takes out an electrical signal from a humoral transmission member in a body fluid analysis apparatus side. For example, the conductive member of the shape of a cylinder corresponding to the pores 22 and 23 of a base 2 is installed in a body fluid analysis apparatus, and if it is made to drive so that a humoral transmission member may be contacted when it equips with a body fluid extraction instrument, the detected matter can be measured even if it does not prepare an electrode and lead wire like this example. Moreover, although this example explained the detected matter taking the case of the approach of measuring electrochemically, a means to detect optically using a GOD-chromophoric substrate etc. is also applicable.

[0035] This body fluid extraction instrument 1 can be made into a cartridge-type, and can be used for a body fluid analysis apparatus. By it, throwing away becomes possible and bacterial infection etc. can be prevented. Moreover, if this body fluid extraction instrument 1 is packed, it becomes safe still more sanitarily and deactivation of an enzyme can also be prevented. The sectional view of the body fluid extraction instrument 1 which twisted package object 11 and was packed is shown in drawing 10. Although this package object 11 may be formed from what kind of thing as long as it has airtightness, the laminate film which carried out two or more laminatings of polyethylene, nylon, the polypropylene, etc., for example to aluminum foil can be used for it. It is desirable to perform a package by the aseptic condition.



[0036] If the body fluid extraction instrument 1 is used as the cartridge of 1 by plurality when making the body fluid extraction instrument 1 into a cartridge-type, it can let out a body fluid extraction instrument one after another, and body fluid can be analyzed continuously. Drawing 11 is the sectional view showing the condition of having loaded the cartridge electrode holder 12 of 1 with five body fluid extraction instruments 1 respectively packed with the package object 11.

[0037] Next, the perspective view of the body fluid extraction instrument by another example of this invention is shown in drawing 12. moreover, the mimetic diagram showing an example of the body fluid extraction which used body fluid extraction instrument 1' for drawing 13 for the top view of the humoral transmission member 4 of body fluid extraction instrument 1' in drawing 12 -- drawing 14 (a), (b), and (c) It is shown. Body fluid extraction instrument 1' has the cylinder-like cylinder 24, the reusable puncture needle attachment component 31 which can slide on the inside of a cylinder 24, the reusable puncture needle 3 attached in the reusable puncture needle attachment component 31, and the humoral transmission member 4 prepared in the soffit of a cylinder 24. As shown in drawing 13, the working electrode 41 and the contrast electrode 42 are formed in the humoral transmission member 4, and wiring 44 is formed in each electrode. Although each electrodes 41 and 42 and wiring 44 may be formed in any of the top face of the humoral transmission member 4, or an underside, when the humoral transmission member 4 consists of an ingredient of non-absorptivity, it is necessary to prepare them in an underside.

[0038] Especially if installation to a body fluid analysis apparatus is possible for the magnitude and the configuration of a cylinder 24, it will not be restricted, but when the operability at the time of installation, the storability of a reusable puncture needle 3, etc. are taken into consideration, the height of the direction of a puncture is 2-50mm, and it is desirable that they are [ whose cross section vertical to the direction of a puncture is the diameter of 3-50mm ] circular or the configuration which combined the ellipse form, the polygon whose one side is 3-50mm or the polygon, and circular and an ellipse form.

[0039] Also in this body-fluid extraction instrument 1', the laminating of the humoral transmission member (water absorption layer) which consists of an ingredient of absorptivity, and the sheet which consists of an ingredient of non-absorptivity may be carried out, and two or more enzyme electrodes may be prepared. Two or more enzyme electrodes may be prepared in the same base material, as shown in drawing 15, a humoral transmission member may be constituted from two or more layers which consist of an absorptivity ingredient, and the enzyme electrode of a class which is different on each class may be prepared. Even case [ like drawing 15 ], an electrode may be prepared between the sheets which consist of a humoral transmission member which a base material may consist of an absorptivity ingredient, and may consist of a non-absorptivity ingredient, or consists of an absorptivity ingredient, and a non-absorptivity ingredient.

[0040] In body liquid extraction instrument 1', the reusable puncture needle attachment component 31 is pushed with the hammer connected with the spring, and slides caudad. By it, a reusable puncture needle 3 penetrates the humoral transmission member 4, and carries out the puncture of the finger with which the bottom of it was equipped. A reusable puncture needle 3 and the reusable puncture needle attachment component 31 return to the original location with a conventional method using an operation of a spring etc. Although the finger by which the puncture was carried out bleeds, the blood is absorbed by the humoral transmission member 4, or is transmitted in between the humoral transmission member 4 and fingers, and reaches electrodes 41 and 42. The detected matter in blood is changed into an electrical signal, and is sent to the sensor formed in the body fluid analysis apparatus through wiring 44.

[0041] Although the body fluid extraction instrument was explained above, the body fluid analysis apparatus of this invention which used this body fluid extraction instrument next is explained. In addition, in this example, a body fluid extraction instrument is considered as a measurement chip.

[0042] Drawing 16 is the perspective view of a body fluid analysis apparatus with an example of this invention. The display 61 and the binding switch 62 with which this body fluid analysis apparatus 5 was formed in the flank of 1 of housing 6 and its housing 6, the reusable puncture needle discharge switch 63, the measurement chip installation implement 64, a test section 80, and the binding section 7, While



having the cartridge electrode-holder stowage 8 and the reusable puncture needle actuator 9 which were established in the interior of housing 6 Measurement chip 81a was installed in the test section 80, and the cartridge electrode holder 82 including the measurement chips 81b, 81c, 81d, and 81e packed with the package object 83 in the cartridge electrode-holder stowage 8 is contained.

[0043] Drawing 17 (a) and (b) The measurement chip 81 contained by the cartridge electrode holder 82 is sent out at a time to a test section 80 by one measurement chip installation implement 64 so that it may be shown. Since the package object 83 is torn off from the measurement chip 81 by claw part 80a prepared in the test section 80 at this time, the measurement chip 81 is installed in a test section 80 in the safe condition for reasons of sanitation. The measurement chip installation implement 64 is formed possible [ sliding ] to the cartridge electrode holder 82, and after it sends out the measurement chip 81, it is returned to the original location with a spring 84. The measurement chips 81b, 81c, 81d, and 81e left behind after measurement chip 81a was sent out are pressed with a spring 85, and measurement chip 81b moves them to the location which may be sent out by the measurement chip installation implement 64.

[0044] Although point 64a of an installation implement is horizontally suitable in the usual condition, for example although you may have what kind of configuration as long as it can send out the measurement chip 81 to a test section 80, and the measurement chip 81 may pass through the bottom of the measurement chip installation implement 64, the measurement chip installation implement 64 In case it is used, if the measurement chip installation implement 64 is touched, when installation implement point 64a contacts the back end section of the measurement chip 81 toward a slanting lower part and slides the measurement chip installation implement 64, the configuration which can send out the measurement chip 81 to a test section 80 can be taken.

[0045] In addition, although the graphic display was not carried out, it is desirable to prepare extrusion and the abolition function which can discard the measurement chip after measurement, without a test subject touching directly. As long as the package object 83 is desorbed from the measurement chip 81, with a desired means, it may have what kind of configuration, but when making it torn off for example, by claw part 80a prepared in the test section 80, can prepare handle part 83a into which the head was divided, and can take a configuration with which claw part 80a enters between the broken part.

[0046] It is prepared in order for the binding section 7 to make the bleeding volume of body fluid increase, and a finger is inserted into this. In this example, although the binding section 7 has become cylinder-like, it can choose various configurations, such as the shape of a ring, and telescopic. Since there is individual difference in the size of the finger of an operating personnel-ed, it is desirable that they are the ingredient which has elasticity, and the thing which can adjust a bore with a belt etc.

[0047] The binding member 71 which makes a finger pressed and congested is formed in the interior of the binding section 7. Except the time of measurement, although this binding member 71 contacts a finger lightly and is fixing that finger to it, at the time of the need (at the time [ For example, a puncture direct front stirrup ] before a puncture - of a puncture), a bore becomes small, and it makes the blood vessel of a finger congested while it presses a finger, and can obtain the body fluid of an amount enough at the time of a puncture. Moreover, the body fluid of an amount can be enough pressed out from a puncture part by pressing a finger immediately after a puncture. Although you may consist of what kind of thing as a binding member 71 as long as it can make a finger pressed and congested, the thing using impregnation of air, the thing using the draw-down of the belt by actuation of a motor etc., etc. can be used like the application-of-pressure band used for measurement of blood pressure, for example.

[0048] The reusable puncture needle (refer to drawing 1 - drawing 3 , and drawing 8 ) of the measurement chip 81 installed in the test section 80 is hammered out with the hammer 92 connected with the spring 91 in the reusable puncture needle actuator 9, and projects from a humoral transmission member. What is necessary is just to establish a means which operates that what is necessary is just to perform actuation of a hammer 92 with a conventional method when the reusable puncture needle discharge switch 63 is pushed. In order to raise visibility, forming as greatly as possible is desirable, and when a display 61 inserts a finger in the binding section 7, it is desirable to prepare in the location in

which it does not hide with the finger.

[0049] An example of the approach of measuring the detected matter in blood is explained using the above-mentioned body fluid analysis apparatus 5. First, the cartridge electrode holder 82 is inserted in the cartridge electrode-holder stowage 8, and the measurement chip 81 is sent out to a test section 80 with the measurement chip installation implement 64. Next, a finger is inserted in the binding section 7 (refer to drawing 18), and the binding switch 62 is turned on. Then, a finger is pressed by the binding member 71 and congested. If the reusable puncture needle discharge switch 63 is turned on in this condition, the reusable puncture needle of the measurement chip 81 will be hammered out with the hammer 92 connected with the spring 91, and will carry out the puncture of a projection and the finger from a humoral transmission member. The blood which bled from the finger is absorbed by the humoral transmission member, or is transmitted in between a humoral transmission member and fingers, reaches an electrode, and the detected matter in blood serves as an electrical signal, it is sent to a sensor, and measured value is shown in a display 61.

[0050] Moreover, another example of the approach of measuring the detected matter in blood is explained using the above-mentioned body fluid analysis apparatus 5. Although it is the same as that of the above until it inserts the cartridge electrode holder 82 in the cartridge electrode-holder stowage 8, and sends out the measurement chip 81 to a test section 80 and inserts a finger in the binding section 7 after that with the measurement chip installation implement 64 next, the reusable puncture needle discharge switch 63 is turned on. Then, the reusable puncture needle of the measurement chip 81 is hammered out with the hammer 92 connected with the spring 91, and carries out the puncture of a projection and the finger from a humoral transmission member. After carrying out a puncture, the binding switch 62 is turned on. Blood is pressed out from the part which the binding member 71 pressed the finger and carried out the puncture by it. The blood which bled is absorbed by the humoral transmission member, or is transmitted in between a humoral transmission member and fingers, reaches an electrode, and the detected matter in blood serves as an electrical signal, it is sent to a sensor, and measured value is shown in a display 61.

[0051] In addition, although the perspective view of body fluid analysis apparatus 5' by another example of this invention which used body fluid extraction instrument 1' mentioned above is shown in drawing 19 and drawing 20, if the fundamental configuration is the same as that of the above-mentioned body fluid analysis apparatus 5 and the reusable puncture needle discharge switch 63 is turned on, the hammer 92 connected with the spring 91 begins to beat the reusable puncture needle attachment component 31, and by it, a reusable puncture needle 3 will be extruded, it will penetrate the humoral transmission member 4, and will carry out the puncture of the finger. What is necessary is to read the echo of light which carried out incidence to the test section, and just to use the device to evaluate, in detecting optically using a GOD-chromophoric substrate etc. although the above example explained the detected matter taking the case of the approach of measuring electrochemically.

[0052] According to the body fluid analysis apparatus of such this invention, by simple switch actuation, after equipping with a measurement chip or a cartridge, while being able to perform a series of actuation processes of pressure of pressure of a finger, a puncture, detection and the display of measured value or a puncture, and a finger, detection, and a display of measured value continuously, inspection can be substituted for one-touch. Moreover, since this equipment possesses all of the means which takes out a puncture member, a humoral transmission member, an electrode, or an electrical signal, the means to which the bleeding volume of body fluid is made to increase, and a display, a general user does not need skill but can use it easily and promptly.

[0053] As mentioned above, although this invention was explained to the detail using the drawing, this invention can perform various modification, unless it deviates from the thought of this invention, without being limited to this. For example, the thing of the shape of two rollers or a wash clip is used instead of a binding member, and body fluid can be pressed out from the skin.

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**EXAMPLE**

[Example] Hereafter, although an example explains this invention still more concretely, the range of this invention is not limited to these examples.

(Example 1) The phosphate buffer (pH7.3) containing a golden sol particle (particle size of about 40nm) and glucose oxidase was agitated, and the enzyme was fixed. Polypyrrole is mixed in this solution and it is a working-electrode component solution (a). It carried out. On the other hand, it is a working-electrode component solution (a). Working-electrode component solution which fixed cholesterol oxidase to the golden sol particle instead of glucose oxidase on the same conditions (b) It prepared.

[0055] It is a working-electrode component solution (a) with a dispenser, respectively to 4n of glass fiber filter papers which formed the golden paste by screen-stencil as the contrast electrode 42 and 42' as shown in drawing 21, and 4n 'two sheets. And (b) Apply, and it is made to dry for 2 minutes at 50 degrees C, and is an enzyme electrode (A). And (B) 41 and 41' was formed. Thus, enzyme electrode (A) And (B) Spacer 4m which consists of the same glass fiber filter paper 4n of glass fiber filter papers in which 41 and 41' was formed, and 4n 'two sheets It minded, and the laminating was carried out and it considered as the humoral transmission member 4. This humoral transmission member 4 was used and body fluid extraction instrument 1" as shown in drawing 22 was manufactured.

[0056] Each electrodes 41 and 42, 41', and 42' It connected with the reader (not shown) through lead wire 43. The finger was equipped with above-mentioned body fluid extraction instrument 1", and it was made to bleed with a reusable puncture needle. Blood was transmitted to enzyme electrode (A) and (B) 41, and 41' through 4n of glass fibers, 4n', and 4m from the puncture section, and was able to detect the glucose concentration and cholesterol concentration in blood with the above-mentioned reader.

[0057] (Example 2) Ferrocene qualification GOD solution 900 which introduced the ferrocene carboxylic acid into the lysine residue of GOD through the carbodiimide mul PVP0.123 g and ethanol 100 mul It mixed and considered as the enzyme electrode component solution. As shown in drawing 23, screen-stencil was used for polystyrene sheet 4b which prepared 4h of puncture holes with a diameter of 2mm with a silver paste, and the substrate and the contrast electrode 42 of a working electrode 41 were formed in it. Furthermore, applied the above-mentioned enzyme electrode component on the working-electrode substrate using screen-stencil, and it was made to dry for 5 minutes at 50 degrees C, and considered as the enzyme electrode.

[0058] After applying completely the solution for water absorption layers which consists of microcrystal cellulose:ethanol:triton X-100=1:1:0.01 by screen-stencil and drying it for 5 minutes at 50 degrees C on polystyrene sheet 4b of the side in which the enzyme electrode was formed, it was made to dry thoroughly by the air dried. thus -- water absorption -- a layer -- four -- a -- having formed -- a sheet -- using it -- water absorption -- a layer -- four -- a -- an underside -- becoming -- making -- drawing 24 -- being shown -- as -- body fluid -- extraction -- an instrument -- one -- " -- having manufactured . They are each electrodes 41 and 42 like an example 1. It measured by connecting with a reader. Consequently, the glucose concentration in blood was detectable.

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**CLAIMS**

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**[Claim(s)]**

[Claim 1] The body fluid extraction instrument characterized by coming at least to provide the humoral transmission member which may be transmitted to the location of a request of body fluid, and the puncture member which may penetrate said humoral transmission member.

[Claim 2] The body fluid extraction instrument according to claim 1 with which said humoral transmission member is characterized by being formed from the ingredient of absorptivity.

[Claim 3] The body fluid extraction instrument according to claim 2 characterized by preparing a kind or two or more sorts of enzyme electrodes in said humoral transmission member.

[Claim 4] The body fluid extraction instrument according to claim 2 characterized by preparing the enzyme electrode of a class which is different on each class by said humoral transmission member consisting of two or more layers.

[Claim 5] The body fluid extraction instrument according to claim 4 characterized by preparing the spacer layer which has absorptivity between the layers in which the enzyme electrode was prepared.

[Claim 6] The body fluid extraction instrument according to claim 2 which the laminating of the sheet which consists of an ingredient of non-absorptivity is carried out on said humoral transmission member currently formed from the ingredient of absorptivity, and is characterized by preparing a kind or two or more sorts of enzyme electrodes between said humoral transmission members and said sheets.

[Claim 7] The body fluid extraction instrument according to claim 2 with which the ingredient of said absorptivity is characterized by being paper, textile fabrics, a nonwoven fabric, or a porous body.

[Claim 8] The body fluid extraction instrument according to claim 7 characterized by said textile fabrics and nonwoven fabric consisting of at least one sort chosen from the group which consists of a cellulose, a regenerated cellulose, cellulose acetate, silk, cotton, a polyamide, polyester, the poly acrylic, polyolefine, polyurethane, and nylon.

[Claim 9] The body fluid extraction instrument according to claim 7 characterized by said porous body consisting of at least one sort chosen from the group which consists of a glass filter, a nylon membrane, a nitrocellulose membrane, a cellulose acetate membrane, a polyvinylidene fluoride membrane, a regenerated-cellulose membrane, and a foaming cellulose sheet.

[Claim 10] The body fluid extraction instrument according to claim 1 which said humoral transmission member is formed from the ingredient of non-absorptivity, and is characterized by preparing a kind or two or more sorts of enzyme electrodes in the underside of said humoral transmission member.

[Claim 11] claims 3, 4, and 6 which said enzyme electrode consists of the working-electrode section and contrast polar zone, and are characterized by this working-electrode section containing the oxidoreductase, the electron transport matter, and the conductive matter of the quality of a detected material, or 10 -- either -- the body fluid extraction instrument of a publication.

[Claim 12] The body fluid extraction instrument according to claim 11 characterized by said conductive matter being a metal sol particle.

[Claim 13] The body fluid extraction instrument according to claim 12 with which it is characterized by being formed by the dispenser, the ink jet, roll coating, or screen printing with said electron transport matter after said working-electrode section fixes said oxidoreductase to said metal sol particle in a water solution.

[Claim 14] claim 1 characterized by packing said body fluid extraction instrument with the package object thru/or 13 -- either -- the body fluid extraction instrument of a publication.

[Claim 15] The body fluid analysis apparatus characterized by coming to provide a body fluid extraction instrument according to claim 1 or 2, the means which takes out an electrical signal from said humoral transmission member, the means to which the bleeding volume of body fluid is made to increase, and the display which displays the analysis result of the extracted body fluid at least.

[Claim 16] The body fluid analysis apparatus characterized by coming to provide claims 3, 4, and 6 or the body fluid extraction instrument of a publication and the means to which the bleeding volume of body fluid is made to increase, and the display that displays the analysis result of the extracted body fluid 10 either at least.

[Claim 17] The body fluid analysis apparatus characterized by coming to provide a body fluid extraction instrument according to claim 14, the means to which the bleeding volume of body fluid is made to increase, the display which displays the analysis result of the extracted body fluid, and a means to desorb said package object from said body fluid extraction instrument at least.

[Claim 18] claim 15 characterized by for one or more said body fluid extraction instruments coming out, and constituting the cartridge of 1 thru/or 17 -- either -- the body fluid analysis apparatus of a publication.

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## DESCRIPTION OF DRAWINGS

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### [Brief Description of the Drawings]

[Drawing 1] It is the perspective view showing an example of the body fluid extraction instrument of this invention.

[Drawing 2] (a) The A-A sectional view of the body fluid extraction instrument in \*\*\*\*1 is shown. (b) The sectional view of the body fluid extraction instrument by other examples of \*\*\*\*\* is shown.

[Drawing 3] The decomposition perspective view of the body fluid extraction instrument in drawing 1 is shown.

[Drawing 4] The enlarged drawing of the electrode formed in the humoral transmission member which consists of an ingredient of absorptivity is shown. (a) The condition that \*\* and an electrode are covered by the front face of the organization of an absorptivity ingredient is shown, and it is (b). While the electrode is covered by the organization chart side, the condition that the opening of an organization is filled up is shown.

[Drawing 5] (a) It is the perspective view showing the laminating of \*\*, the humoral transmission member (water absorption layer) which consists of an ingredient of absorptivity, and the sheet which consists of an ingredient of non-absorptivity, and is (b). The sectional view is shown.

[Drawing 6] It is the perspective view showing an example of the humoral transmission member which consists of two or more layers.

[Drawing 7] It is the perspective view showing other examples of the humoral transmission member which consists of two or more layers.

[Drawing 8] It is the mimetic diagram showing extraction of the puncture and body fluid using a body fluid extraction instrument with an example of this invention. (a) The condition and (b) which are \*\*\*\*\* (ing) The condition just behind a puncture is shown.

[Drawing 9] It is the mimetic diagram showing extraction of the puncture and body fluid using the body fluid extraction instrument by other examples of this invention. (a) The condition and (b) which are \*\*\*\*\* (ing) The condition just behind a puncture is shown.

[Drawing 10] It is the sectional view showing the body fluid extraction instrument which this invention packed.

[Drawing 11] It is the sectional view showing the body fluid extraction instrument of this invention contained in the cartridge electrode holder.

[Drawing 12] It is the perspective view showing another example of the body fluid extraction instrument of this invention.

[Drawing 13] It is the top view showing an example of the humoral transmission member in the body fluid extraction instrument of drawing 7.

[Drawing 14] It is the mimetic diagram showing extraction of the puncture and body fluid using the body fluid extraction instrument by another example of this invention. (a) The condition in front of \*\*\*\*\*; and (b) The condition and (c) which are carrying out the puncture The condition just behind a puncture is



shown.

[Drawing 15] It is the top view showing other examples of the humoral transmission member in the body fluid extraction instrument of drawing 7.

[Drawing 16] It is the perspective view showing an example of the body fluid analysis apparatus of this invention.

[Drawing 17] It is the sectional view showing the body fluid extraction instrument (measurement chip) of this invention contained in the cartridge electrode holder. (a) The condition before sending out a \*\*\*\*\* chip, and (b) The condition after sending out a measurement chip is shown.

[Drawing 18] It is the perspective view showing the condition of having equipped the body fluid analysis apparatus with an example of this invention with the finger.

[Drawing 19] It is the perspective view showing another example of the body fluid analysis apparatus of this invention.

[Drawing 20] It is the perspective view showing the condition of equipping with and carrying out the puncture of the finger to the body fluid analysis apparatus by another example of this invention.

[Drawing 21] It is the perspective view showing the humoral transmission member in an example 1.

[Drawing 22] It is the sectional view showing the body fluid extraction instrument in an example 1.

[Drawing 23] It is the perspective view showing the humoral transmission member in an example 2.

[Drawing 24] It is the sectional view showing the body fluid extraction instrument in an example 2.

[Description of Notations]

1, 1', and 1 -- ", 1'" -- body fluid extraction instrument

11 83 -- Package object

12 82 -- Cartridge electrode holder

2 -- Base

21, 22, 23 -- Pore

24 -- Cylinder

3 -- Reusable puncture needle

31 -- Reusable puncture needle attachment component

4, 4n, 4n', 4n" -- Humoral transmission member

4m, 4m' -- Spacer layer

4a -- Water absorption layer

4b -- Sheet

4t -- Organization of an absorptivity ingredient

4h -- Puncture hole

40 -- Electrode

41 41' -- Working electrode

42 42' -- Contrast electrode

43 -- Lead wire

44 -- Wiring

5 5' -- Body fluid analysis apparatus

6 -- Housing

61 -- Display

62 -- Binding switch

63 -- Reusable puncture needle discharge switch

64 -- Measurement chip installation implement

64a -- Installation implement point

7 -- Binding section

71 -- Binding member

8 -- Cartridge electrode-holder stowage

80 -- Test section

80a -- Claw part  
81 a-e -- Measurement chip  
83a -- Package object handle part  
84, 85, 91 -- Spring  
9 -- Reusable puncture needle actuator  
92 -- Hammer

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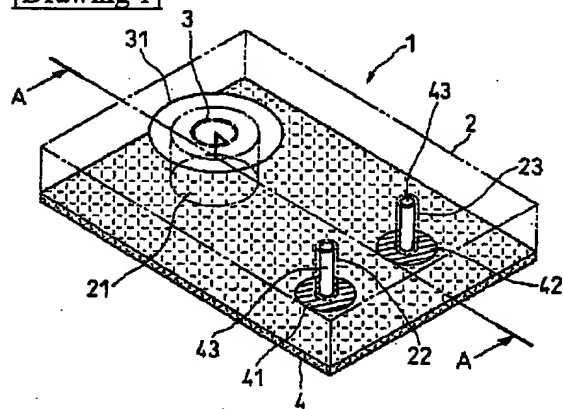
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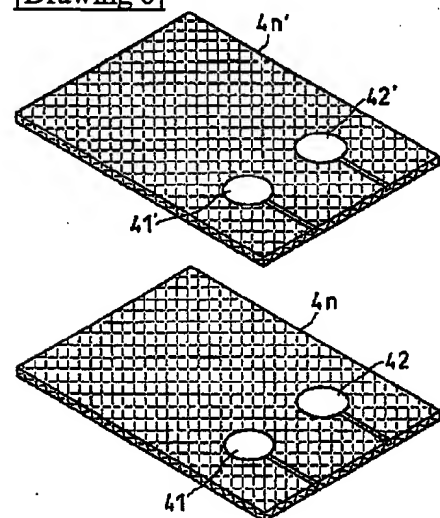
**DRAWINGS**

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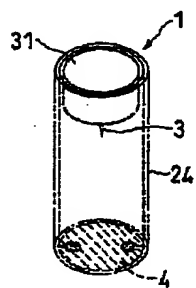
**[Drawing 1]**



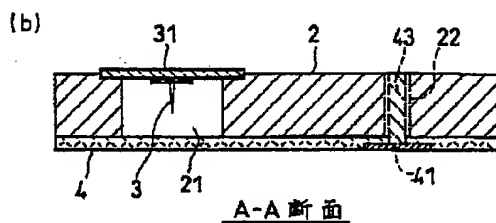
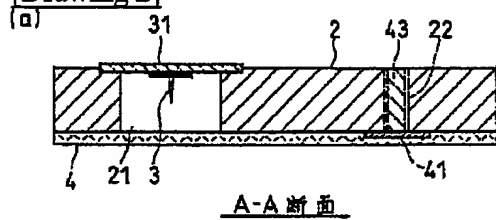
**[Drawing 6]**



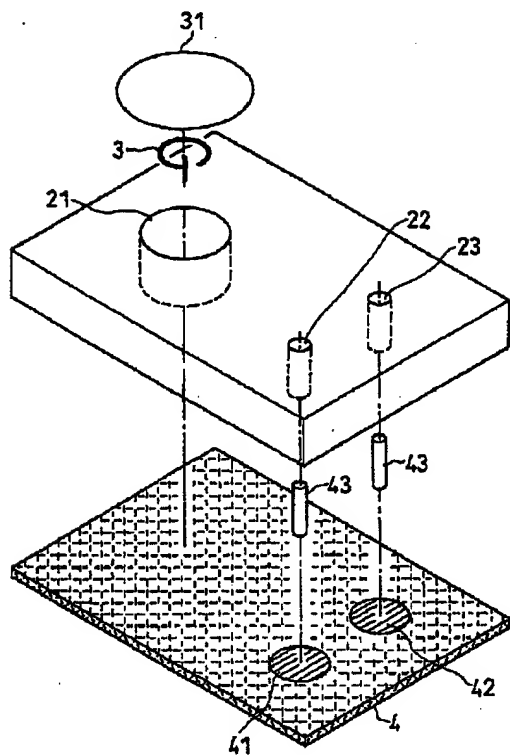
**[Drawing 12]**



[Drawing 2]

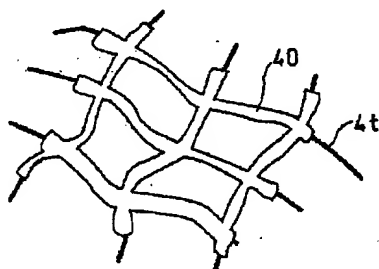


[Drawing 3]

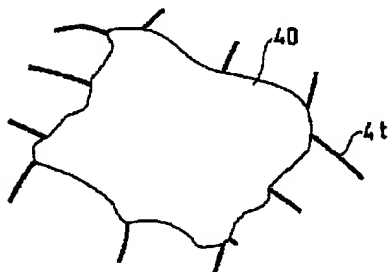


[Drawing 4]

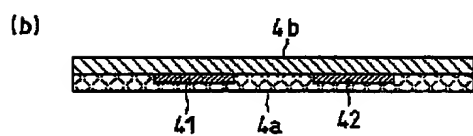
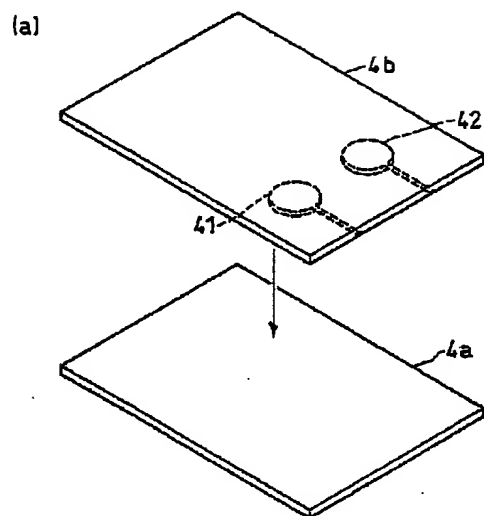
(a)



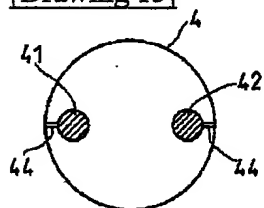
(b)



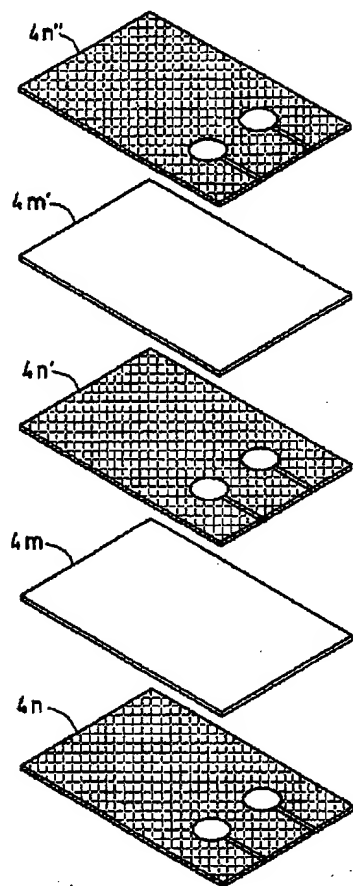
[Drawing 5]



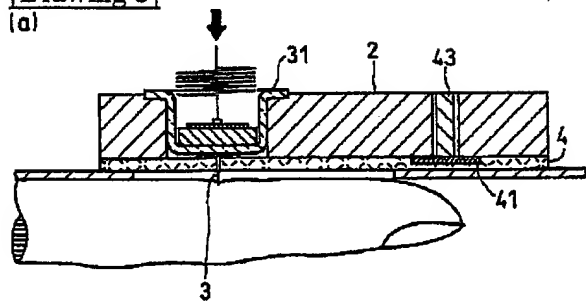
[Drawing 13]



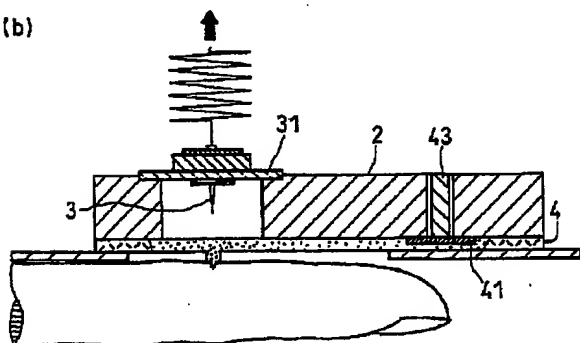
[Drawing 7]



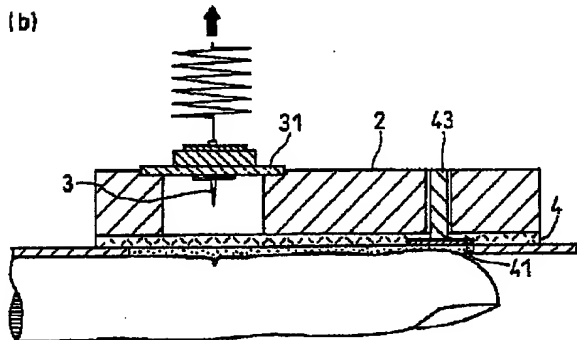
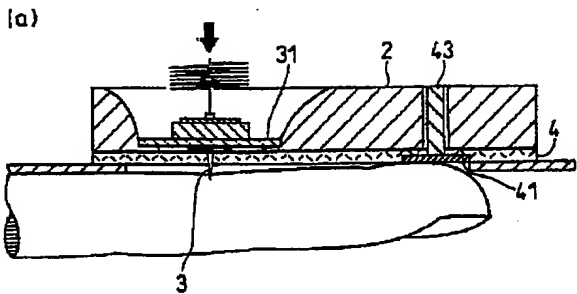
[Drawing 8]



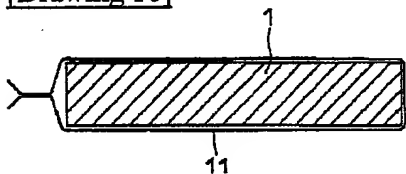
(b)



[Drawing 9]



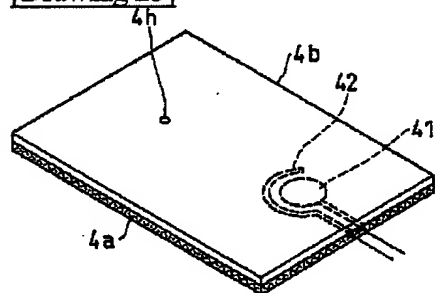
[Drawing 10]



[Drawing 11]

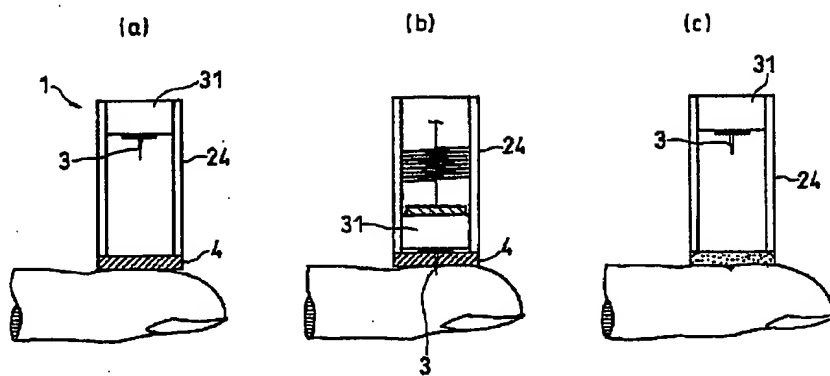


[Drawing 23]

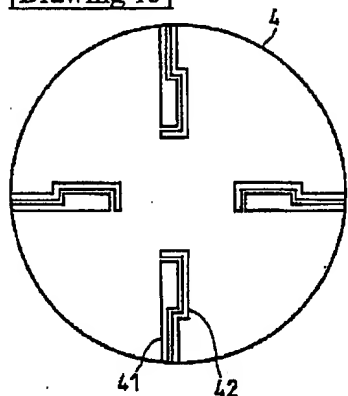


[Drawing 14]

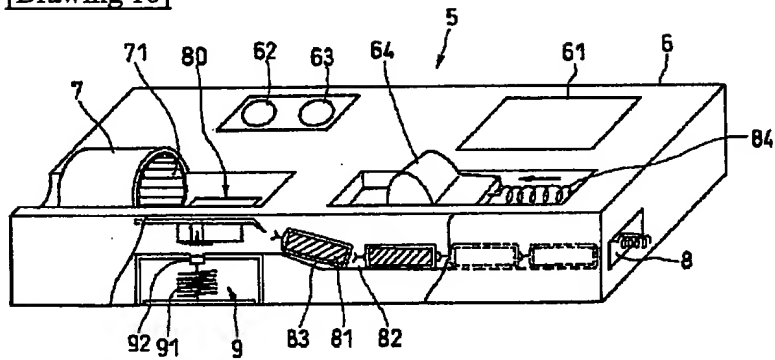




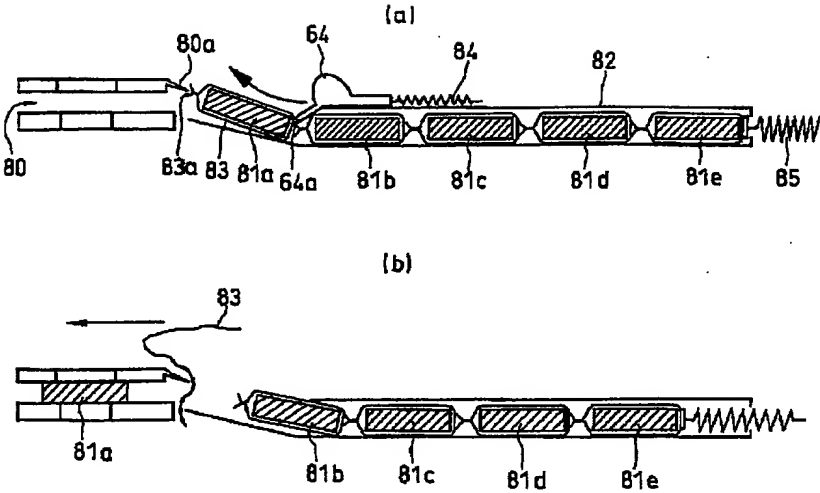
[Drawing 15]



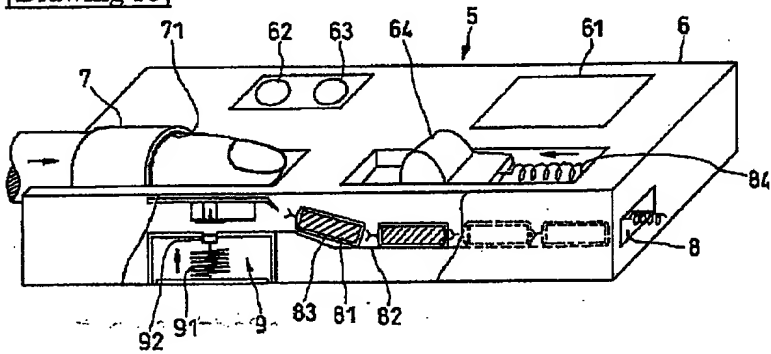
[Drawing 16]



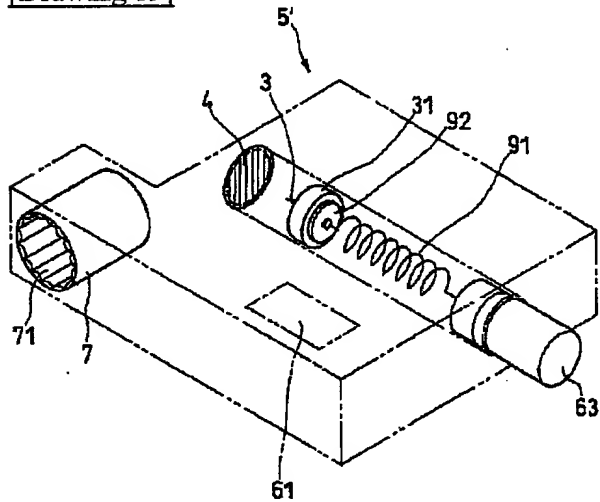
[Drawing 17]



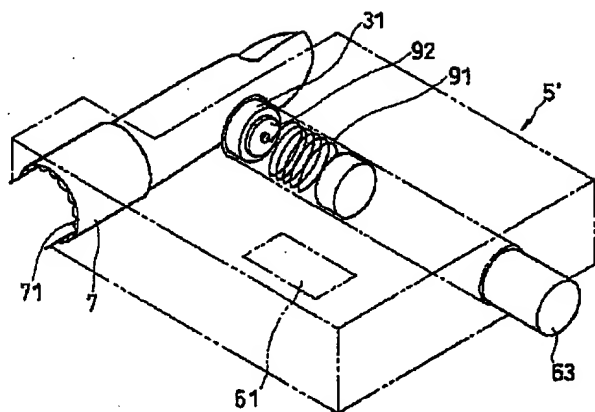
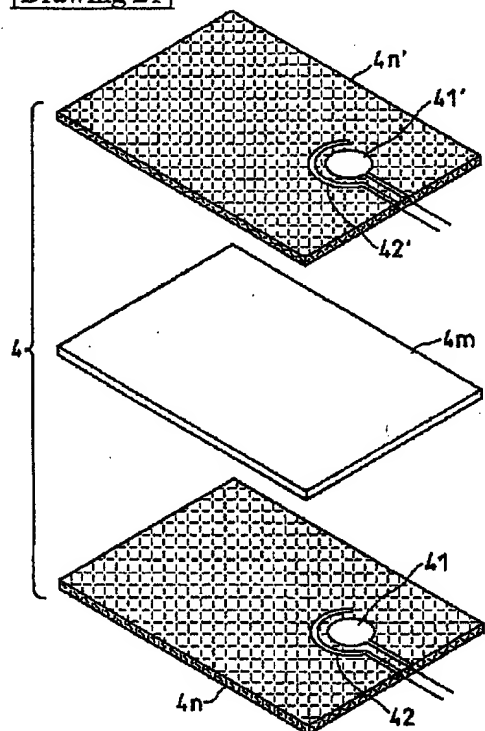
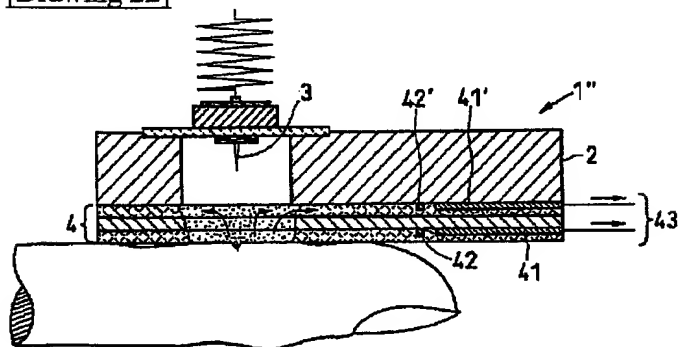
[Drawing 18]

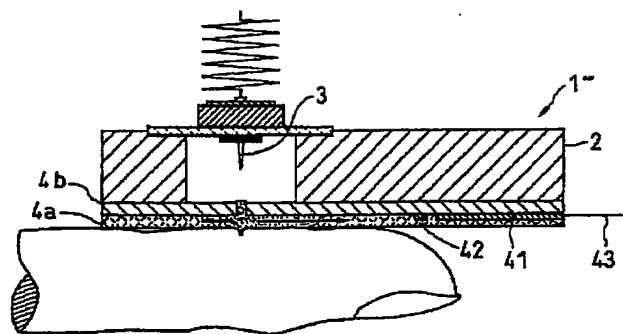


[Drawing 19]



[Drawing 20]

[Drawing 21][Drawing 22][Drawing 24]



[Translation done.]

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